

### REMARKS

Claims 1, 3 to 11, 13 to 18, 27, 28, and 36 to 40 are pending in this application. Applicant has added new claims 36 to 40. Support for the new claims can be found throughout the specification as filed, e.g., at page 7, lines 11-16. The new claims add no new matter to the specification.

Applicant thanks Examiner Vogel for her time to conduct a telephonic interview on March 2, 2006, with the undersigned. The last outstanding rejection was discussed. Applicant's representative understood the Examiner to suggest, but not promise, that one potential way to overcome the present rejection would be for applicant to provide evidence that the *panB* promoter of *Escherichia coli* was known (thereby providing evidence that a *panB* promoter exists in both Gram negative and Gram positive bacteria) and that the *panB* gene was known in a variety of bacterial genera. Applicant's arguments presented below provide that evidence.

#### Objection and Allowable Subject Matter

Applicant acknowledges the Office's finding that claims 3 and 13 would be allowable if rewritten in independent form. Applicant believes that the base claims will be allowed in view of the arguments presented below, rendering the present objection moot. Accordingly, applicant respectfully requests that the objections to claims 3 and 13 be withdrawn and the claims allowed.

#### Withdrawn Objections and Rejections

While the Examiner did not explicitly withdraw any previous objections or rejections, applicant assumes that all prior objections and rejections not reasserted in the present Office Action are withdrawn. Thus, applicant acknowledges the withdrawal of the following:

1. the objection to claims 2, 12, and 19 for an alleged informality;
2. the rejection of claim 1 as allegedly anticipated by Rohlman et al. (J. Bacteriol. 172(12):7200-7210 (1990)); and
3. the rejection of claim 26 as allegedly anticipated by Tan et al. (EP 0200252).

Applicant understands that only one rejection remains outstanding in this application, i.e., the rejection of claims 1, 4 to 11, 14 to 18, 27, and 28 for an alleged lack of written description.

### The Invention

Tetrahydrofolate is an essential cofactor for many biosynthetic enzymes. For example, the enzyme ketopantoate hydroxymethyl transferase, encoded by the *panB* gene, requires a tetrahydrofolate cofactor to synthesize precursors of pantothenate. The applicant has determined that the activity of the promoter for the *panB* gene is increased in the presence of compounds that inhibit bacterial tetrahydrofolate biosynthesis. The present application takes advantage of this special characteristic. The application provides various methods, e.g., methods for determining whether a test compound is a potential tetrahydrofolate biosynthesis inhibitor by determining whether the compound induces increased *panB* promoter activity. The activity of the *panB* promoter can be measured in a number of ways, e.g., by measuring the expression product of a reporter gene linked to the promoter.

### Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 4 to 11, 14 to 18, 27 and 28 were rejected for allegedly failing to comply with the written description requirement. The Office Action states (at page 3):

Claims 1, 4-11, 14-18, 27 and 28 are genus claims in terms of a method using any bacteria containing any *panB* promoter, whose activity is increased in the presence of a compound that inhibits tetrahydrofolate biosynthesis. The claims encompass a broad class of methods using a promoter that may be any *panB* promoter that has this function.

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There is no disclosure of *panB* promoters having the recited activity, from any other bacteria of plant, or any indication that *panB* promoters from other organisms are homologous to the disclosed *panB* promoter shown in SEQ ID NO:1. Therefore, the specification does not describe the claimed method utilizing *panB* promoters which have increased activity in the presence of a compound that inhibits tetrahydrofolate activity, in such clear, concise and

exact terms as to indicate that Applicant had possession of the method at the time of filing the present application.

Applicant respectfully traverses this rejection. As applicant respectfully pointed out in the previous Reply, the specification provides a clear written description of the general use of bacterial *panB* promoters in applicant's new methods. The specification indicates that a *panB* promoter, or any other promoter whose activity is upregulated by a tetrahydrofolate biosynthesis inhibitor, can be used in the methods of the present invention (see, e.g., page 2, lines 26 to 28 and page 3, lines 7 to 14).

The application provides the nucleic acid sequence of one *Bacillus subtilis panB* promoter (at, e.g., page 14, line 22 to page 15, line 3) that can be used in the claimed methods. However, it is clear that *panB* promoters other than the one disclosed in the present specification were known at the time the present application was filed. For example, the *panB* promoter of *Escherichia coli* was known. As evidence thereof, applicant provides herewith a publication by Jones et al. (J. Bacteriol. 175(7):2125-2130 (1993); a copy of which is attached hereto as Exhibit A), which discloses the sequence of the *E. coli panB* gene and the *E. coli panB* promoter. It is also clear that *panB* genes from a variety of bacterial genera other than *Bacillus* were known at the time of filing. For example, the instant specification discloses at page 4, line 16, a reference by Cronan et al. (J. Bacteriol., 149(3):916-922 (1981); a copy of which is attached hereto as Exhibit B), which describes genetic and enzymatic characterization of pantothenate auxotrophs *Salmonella typhimurium* and *E. coli* and describes the *panB* gene from both organisms. As another example, applicants attach hereto (as Exhibit C) a publication by Sahm et al. (App. Env. Microbiol., 65(5):1973-1979 (1999)), which discloses and characterizes the *panB* gene of *Corynebacterium glutamicum*.

Based on the detailed teachings of the present specification and what was known about the *panB* gene at the time of filing, skilled practitioners would have readily appreciated that any bacterial *panB* promoter could be used in the recited methods and would have understood applicant to be in possession of the full scope of the claimed invention. Applicant thus submits

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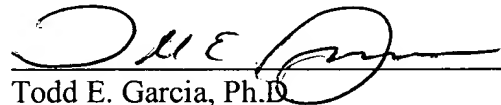
that the claims are in full compliance with the written description requirement and respectfully requests that the present rejection be reconsidered and withdrawn.

CONCLUSION

Applicant submits that all claims are in condition for allowance, which action is requested. Enclosed is a \$1,020 check for the Petition for Extension of Time fee for a three month extension. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney's Docket Number 15132-292001.

Respectfully submitted,

Date: 3/8/06

  
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